

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

BACHMANN *et al.*

Appl. No. 10/622,064

Filed: July 18, 2003

For: **Hapten-Carrier Conjugates and  
Uses Thereof**

Confirmation No.: 5977

Art Unit: 1645

Examiner: *To be assigned*

Atty. Docket: 1700.0300001/BJD/SJE

**First Supplemental Information Disclosure Statement**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed herewith in connection with the above-captioned application. A copy of documents **AO5** to **AN9**; and **AR130** to **AT144** is provided.

Copies of documents **AC3** to **AB4** are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "[t]he Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003."

In accordance with 37 C.F.R. 1.98(a)(3), Applicants' undersigned representative submits the following concise explanation of the relevance of the non-English language documents, Documents AO5, AL6, AM7, AL9, and AM9 cited on Form PTO-1449:

Document AO5, WO 92/03163 A1, is in the German language. The relevance of Document AO5 can be ascertained by reference to the English language abstract appearing therein, and an unverified English language abstract attached as Document AS142;

Document AL6, EP 0 576 357 B1, is in the French language. The relevance of Document AL6 can be ascertained by reference to the English language claims appearing therein, and an unverified English language abstract attached as Document AT142;

Document AM7, WO 00/00462 A1, is in the French language. The relevance of Document AM7 can be ascertained by reference to the English language abstract appearing therein, and an unverified English language abstract attached as Document AR143;

Document AL9, WO 03/040105 A1, is in the French language. The relevance of Document AL9 can be ascertained by reference to the English language abstract appearing therein, and an unverified English language abstract attached as Document AS143;

Document AM9, EP 0 656 354 B1, is in the French language. The relevance of Document AM9 can be ascertained by reference to the English language claims appearing therein, and an unverified English language abstract attached as Document AT144.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates

should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

This First Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Brian J. Del Buono  
Attorney for Applicants  
Registration No. 42,473

Date: Nov. 17, 2003

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FORM PTO-1449  <u>FIRST SUPPLEMENTAL</u> <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 1700.0300001/BJD/SJE	APPLICATION NO. 10/622,064
	APPLICANT BACHMANN et al.	
	FILING DATE July 18, 2003	GROUP 1645

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC3	3,819,706	06/25/1974	Mehta			11/30/1970
	AD3	3,885,046	05/20/1975	Mehta			08/23/1973
	AE3	3,888,866	06/10/1975	Leute et al.			06/01/1973
	AF3	4,123,431	10/31/1978	Soffer et al.			05/06/1977
	AG3	4,197,237	04/08/1980	Leute et al.			02/12/1975
	AH3	4,788,189	11/29/1988	Glazer			02/29/1988
	AI3	4,918,166	04/17/1990	Kingsman et al.			10/26/1987
	AJ3	5,256,409	10/26/1993	Blincko			01/25/1991
	AK3	5,876,727	03/02/1999	Swain et al.			09/30/1996

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	A05	WO 92/03163 A1	03/05/1992	WIPO			Yes No X
	AP5	WO 92/21333 A2	12/10/1992	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	130	Abad, A., et al., "Comparison of a Monoclonal Antibody-Based Enzyme-Linked Immunosorbent Assay and Gas Chromatography for the Determination of Nicotine in Cigarette Smoke Condensates," <i>Anal Chem.</i> 65:3227-3231, American Chemical Society (1993)	
AS	130	Bonese, K.F., et al., "Changes in heroin self-administration by a rhesus monkey after morphine immunisation," <i>Nature</i> 252:708-710, Nature Publishing Group (1974)	
AT	130	Byrnes-Blake, K.A., et al., "Generation of anti-(+)methamphetamine antibodies is not impeded by (+)methamphetamine administration during active immunization of rats," <i>Int. Immunopharmacol.</i> 1:329-338, Elsevier (February 2001)	

EXAMINER	DATE CONSIDERED
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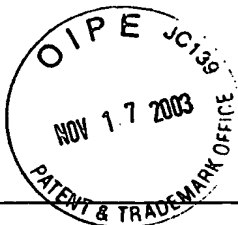
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA4	5,939,598	08/17/1999	Kucherlapati et al.			07/30/1992
	AB4	6,232,082 B1	05/15/2001	Ennifar et al.			12/01/1998
	AC						
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL6	EP 0 576 357 B1	12/29/1993	Europe			X Yes No
	AM6	WO 94/28888 A1	12/22/1994	WIPO			Yes No
	AN6	WO 96/02248 A1	02/01/1996	WIPO			Yes No
	AO6	WO 98/14216 A2	04/96/1998	WIPO			Yes No
	AP6	WO 99/17803 A1	04/15/1999	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	131	Carpino, L.A., "1-Hydroxy-7-azabenzotriazole. An Efficient Peptide Coupling Additive," J. Am. Chem. Soc. 115:4397-4398, American Chemical Society (1993)	
AS	131	Carrera, M.R., et al., "Suppression of psychoactive effects of cocaine by active immunization," Nature 378:727-730, Nature Publishing Group (1995)	
AT	131	Carrera, M.R., et al., "Cocaine vaccines: Antibody protection against relapse in a rat model," Proc. Natl. Acad. Sci. USA 97:6202-6206, National Academy Press (2000)	

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### FOREIGN PATENT DOCUMENTS

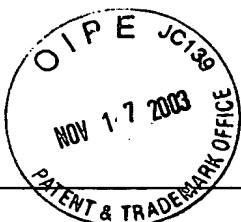
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL7	WO 99/61054 A1	12/02/1999	WIPO			Yes No
	AM7	WO 00/00462 A1	01/06/2000	WIPO			Yes X No
	AN7	WO 00/32227 A3	06/08/2000	WIPO			Yes No
	AO7	WO 01/12176 A2	02/22/2001	WIPO			Yes No
	AP7	WO 01/12176 A3	02/22/2001	WIPO			Yes No

### OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	132	Carrera, M.R., et al., "A second-generation vaccine protects against the psychoactive effects of cocaine," <i>Proc. Natl. Acad. Sci. USA</i> 98:1988-1992, National Academy Press (February 2001)
AS	132	Castaldi, G., et al., "Tartaric Acid, an Efficient Chiral Auxiliary: New Asymmetric Synthesis of 2-Alkyl-2-arylacetic Acids," <i>J. Org. Chem.</i> 52:3018-3027, American Chemical Society (1987)
AT	132	Castro, A., and Prieto, I., "Nicotine antibody production: comparison of two nicotine conjugates in different animal species," <i>Biochem. Biophys. Res. Commun.</i> 67:583-589, Academic Press (1975)

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL8	WO 01/77158 A1	10/18/2001	WIPO			Yes No
	AM8	WO 01/85208 A3	11/15/2001	WIPO			Yes No
	AN8	WO 01/98333 A2 & A3	12/27/2001	WIPO			Yes No
	AO8	WO 02/14478 A2	02/21/2002	WIPO			Yes No
	AP8	WO 02/056905 A2	07/25/2002	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	133	Castro, A., et al, "Nicotine Antibodies: Comparison of Ligand Specificities of Antibodies Produced against Two Nicotine Conjugates," <i>Eur. J. Biochem.</i> 104:331-340, Blackwell Publishing (1980)	
AS	133	Cohen, C., et al., "SR141716, a central cannabinoid (CB <sub>1</sub> ) receptor antagonist, blocks the motivational and dopamine-releasing effects of nicotine in rats," <i>Behav. Pharmacol.</i> 13:451-463, Lippincott Williams & Wilkins (2002)	
AT	133	da Costa, C.L., et al., "Stopping Smoking: A prospective, Randomized, Double-Blind Study Comparing Nortriptyline to Placebo," <i>Chest</i> 122:403-408, The American College of Chest Physicians (August 2002)	

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	AL9	WO 03/040105 A1	05/15/2003	WIPO			Yes X No
	AM9	EP 0 656 354 B1	06/07/1995	Europe			Yes X No
	AN9	WO 02/058635 A2 & A3	08/01/2002	WIPO			Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	134	Fox, B.S., et al., "Efficacy of a therapeutic cocaine vaccine in rodent models," Nat. Med. 2:1129-1132, Nature Publishing Group (1996)	
AS	134	Hardin, J.S., et al., "Pharmacodynamics of a Monoclonal Antiphencyclidine Fab with Broad Selectivity for Phencyclidine-Like Drugs," J. Pharmacol. Exp. Ther. 285:1113-1122, The American Society for Pharmacology and Experimental Therapeutics (1998)	
AT	134	Hieda, Y., et al., "Vaccination against nicotine during continued nicotine administration in rats: immunogenicity of the vaccine and effects on nicotine distribution to brain," Int. J. Immunopharmacol. 22:809-819, Elsevier Science Ltd. (2000)	

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

### OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>135</u>	Hieda, Y., et al., "Active Immunization Alters the Plasma Nicotine Concentration in Rats," <i>J. Pharmacol. Exp. Ther.</i> 283:1076-1081, The American Society for Pharmacology and Experimental Therapeutics (1997)
	AS	<u>135</u>	Hieda, Y., et al., "Immunization of rats reduces nicotine distribution to brain," <i>Psychopharmacology (Berl)</i> 143:150-157, Springer-Verlag (1999)
	AT	<u>135</u>	Hodge, L.M., et al., "Immunoglobulin A (IgA) Responses and IgE-Associated Inflammation along the Respiratory Tract after Mucosal but Not Systemic Immunization," <i>Infect. Immun.</i> 69:2328-2338, American Society for Microbiology (April 2001)

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	AO						Yes No
	AP						Yes No

### OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>136</u>	Isomura, S., et al., "An Immunotherapeutic Program for the Treatment of Nicotine Addiction: Hapten Design and Synthesis," <i>J. Org. Chem.</i> 66:4115-4121, American Chemical Society (June 2001)
	AS	<u>136</u>	Jorenby, D.E., et al., "A controlled trial of sustained-release bupropion, a nicotine patch, or both for smoking cessation," <i>N. Engl. J. Med.</i> 340:685-691, Massachusetts Medical Society (1999)
	AT	<u>136</u>	Joseph, A.M., et al., "Lack of Efficacy of Transdermal Nicotine in Smoking Cessation," <i>N. Engl. J. Med.</i> 341:1157-1158, Massachusetts Medical Society (1999)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>137</u>	Killian, A., et al., "Effects of Passive Immunization Against Morphine on Heroin Self-Administration," <i>Pharmacol. Biochem. Behav.</i> 9:347-352, ANKHO International Inc. (1978)
	AS	<u>137</u>	Klovins, J., et al., "Nucleotide sequence of a ssRNA phage from <i>Acinetobacter</i> : kinship to coliphages," <i>J. Gen. Virol.</i> 83:1523-1533, Cambridge University Press (June 2002)
	AT	<u>137</u>	Langone, J.J. & VanVunakis, H., "Radioimmunoassay of Nicotine, Cotinine, and $\gamma$ -(3-Pyridyl)- $\gamma$ -oxo-N-methylbutyramide," <i>Methods Enzymol.</i> 84:628-640, Academic Press (1982)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	138	Langone, J.J., et al., "Nicotine and Its Metabolites. Radioimmunoassays for Nicotine and Cotinine," <i>Biochemistry</i> 12:5025-5030, American Chemical Society (1973)	
AS	138	Malin, D.H., et al., "Passive immunization against nicotine prevents nicotine alleviation of nicotine abstinence syndrome," <i>Pharmacol. Biochem. Behav.</i> 68:87-92, Elsevier Science (January 2001)	
AT	138	Matsushita, H., et al., "Conjugate of bovine serum albumin with nicotine," <i>Biochem. Biophys. Res. Commun.</i> 57:1006-1010, Academic Press, Inc. (1974)	

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	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>139</u>	Meijler, M.M., et al., "A New Strategy for Improved Nicotine Vaccines Using Conformationally Constrained Haptens," <i>J. Am. Chem. Soc.</i> 125:7164-7165, American Chemical Society (June 2003)
	AS	<u>139</u>	Musso, D.L., et al., "Synthesis and Evaluation of the Antidepressant Activity of the Enantiomers of Bupropion," <i>Chirality</i> 5:495-500, Wiley-Liss, Inc. (1993)
	AT	<u>139</u>	Noguchi, M., et al., "Conjugate of nicotine and cotinine to bovine serum albumin," <i>Biochem. Biophys. Res. Commun.</i> 83:83-86, Academic Press, Inc. (1978)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

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	AR	140	Pentel, P.R., et al., "A Nicotine Conjugate Vaccine Reduces Nicotine Distribution to Brain and Attenuates Its Behavioral and Cardiovascular Effects in Rats," <i>Pharmacol. Biochem. Behav.</i> 65:191-198, Elsevier Science (2000)
	AS	140	Proksch, J.W., et al., "Anti-Phencyclidine Monoclonal Antibodies Provide Long-Term Reductions in Brain Phencyclidine Concentrations during Chronic Phencyclidine Administration in Rats," <i>J. Pharmacol. Exp. Ther.</i> 292:831-837, The American Society for Pharmacology and Experimental Therapeutics (2000)
	AT	140	Simecka, J.W., et al., "Mucosally Induced Immunoglobulin E-Associated Inflammation in the Respiratory tract," <i>Infect. Immun.</i> 68:672-679, American Society for Microbiology (2000)

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	FILING DATE July 18, 2003	GROUP 1645

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>141</u>	"Sindbis Expression System," Version E, Invitrogen Corporation, Carlsbad, CA, Catalog No. K750-1 (April 2002)
	AS	<u>141</u>	Stoll, E., et al., "Revised Amino Acid Sequence of Q $\beta$ Coat Protein between Positions 1 and 60," <i>J. Biol. Chem.</i> 252:990-993, The American Society for Biochemistry and Molecular Biology (1977)
	AT	<u>141</u>	Yamamoto, S., et al., "A nontoxic mutant of cholera toxin elicits Th2-type responses for enhanced mucosal immunity," <i>Proc. Natl. Acad. Sci. USA</i> 94:5267-5272, National Academy Press (1997)

EXAMINER	DATE CONSIDERED
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>142</u>	NCBI Entrez, GenBank Report, Accession No. NP_695026, from Inokuchi et al. (July 2003)
	AS	<u>142</u>	Dialog File 351, Accession No. 8799418, Derwent WPI English language abstract for WO 92/03163 (Document A05)
	AT	<u>142</u>	Dialog File 351, Accession No. 9721628, Derwent WPI English language abstract for EP 0 576 357 (Document AL6)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>143</u>	Dialog File 351, Accession No. 12999043, Derwent WPI English language abstract for WO 00/00462 (Document AM7)
	AS	<u>143</u>	Dialog File 351, Accession No. 15395298, Derwent WPI English language abstract for WO 03/040105 (Document AL9)
	AT	<u>143</u>	Jegerlehner, A., et al., "A molecular assembly system that renders antigens of choice highly repetitive for induction of protective B cell responses," Vaccine 20:3104-3112, Elsevier Science, Ltd. (August 2002)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>144</u>	The Biology of Animal Viruses, 2nd ed., Fenner, F., et al., eds., Academic Press, New York, NY, pp. 117-119 (1974)
	AS	<u>144</u>	NCBI Entrez, PubMed Abstract, PMID: 2205968, Diallo, A., et al., "Morbillivirus group: genome organization and proteins," Vet. Microbiol. 23:155-163 (1990)
	AT	<u>144</u>	Dialog File 351, Accession No. 10300677, Derwent WPI English language abstract for EP 0 656 354 B1 (Document AM9)

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